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10/822,154

04/09/2004

Manne Satyanarayana Reddy

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10/16/2006

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EXAMINER

SEAMAN, D MARGARET M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,154

Applicant(s)

REDDY ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-33 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application was filed 4/9/2004. Claims 1-33 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The rejection of claim 30 under 35 U.S.C. 112, second paragraph, is withdrawn due to applicant's amendments of paper dated 8/11/2006.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 1-4, 6-33 under 35 U.S.C. 102(b) as being anticipated by Grunenberg (US Patent #5849752), is upheld. As previously stated, Grunenberg teaches a crystalline form of anhydrous moxifloxacin monohydrochloride and provides several drawings of different scans that appear to have the same peaks as instantly claimed. Specifically, the figure FIG 4A of Grunenberg has peaks of X-ray diffraction pattern that include peaks at approximately 5.6, 8.4, 10.0, 10.4, 13.1, 13.9 and 14.4. These peaks fit the requirements for claims 2-4. Claim 5 is not included because the X-ray diffraction pattern of fig 1 is distinctly different than the one provided in Fig 4A of Grunenberg.

The ^{13}C solid-state NMR spectrum of claims 6-7 appear to be the same because the scale of the two figures is different to such an extent that a true comparison cannot be made. The same is the same for the infrared absorption spectrum and the spectrum from Grunenberg has bands (note that the "bands" have not been identified as having a value of strong, weak or medium band) at about 1159 and 2706 which fit claim 8. Due to this comparison and the claims having claimed the peaks that are the same as the prior art, the composition remains rejected as in the previous office action.

Applicant argues that the form III shows several less prominent peaks at certain points. However, this is not being claimed. Specifically, prominent (has a value of what?) as compared to less prominent varies from situation to situation. Claims drawn to compounds of form III having the spectrum as shown in fig [some number] clearly having the same scale as the spectrum of the prior art and clearly having a different spectrum, would differentiate the instant form III from the prior art anhydrous form

Further, applicant argues that two articles discuss that different polymorphs show different solubilities and rates of solution. However, this difference in solubilities and rates of solution have not been shown by applicant. A comparison between the prior art compound and the instant compound's rates of solubilities and rates of solution would be a showing towards allowance (however, the claims need to be limited to the showing of the comparison).

Also, applicant argues that Grunenberg does not disclose the making of monohydrate moxifloxacin hydrochloride. However, the processes appear to be the

same and the spectrum (with the exception of the X-ray spectrum) appear to be the same due to different scales of the spectrum.

Claim Objections

4. Claim 5 is objected to because of the following informalities: It depends from a rejected base claim. Appropriate correction is required.

Conclusion

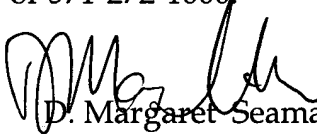
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms